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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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Docket No. 99D-0557

Introduction

The following comments are presented on behalf of our more than 600,000 members in response to a Food and Drug Administration (FDA) "industry guidance" notice published in the Federal Register on "Public Health Issues Posed by the Use of Nonhuman Primate Xenografts."

Hidden Dangers

While the FDA has implemented a ban on the transplantation of vital organs, cells, and tissues from nonhuman primates to humans due to "significant infectious disease risk," the agency has either failed to admit or recognize the dangers posed by transplants from other species.

Pigs, having become the species of choice among the various companies vying for a piece of the animal organ market, pose an equally significant risk to human health. Pigs carry a number of known as well as unknown viruses that could "jump" from one species to another as a result of xenografts. In 1996, virologists at the National Institute for Medical Research in London discovered a pair of viruses called porcine endogenous retrovirus-A and -B. Both of the viruses belong to a family that includes the human immunodeficiency virus (HIV), which causes AIDS and both can infect human cells. Pigs can also harbor swine influenza, Australian paramyxovirus; a novel strain of Hepatitis E, Japanese Encephalitis (JE), and the "Nipah" virus which has infected over 250 humans, killed 100, and led to the slaughter of millions of pigs in Malaysia. These dangers have led the British Government to place a moratorium on all xenografts.

Human Victims

The human immune system is designed to identify and reject foreign objects. Human-to-human transplants have relied on immunosuppressive drugs to control rejection of transplanted organs. Genetic differences make transplants from other species particularly noticeable to the human immune system. Even chimpanzees, our closest relatives, are six times as different from us as we are from each other, and the risk of rejecting a baboon organ is 25 times greater than for an unmatched human organ. Xenograft researchers have developed

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increasingly powerful immunosuppressive therapies to try to overcome this natural reaction. Without exception these treatments create an immune deficiency that leaves the already ill recipient vulnerable to fatal infections.

As with any hazardous medical procedure, xenograft recipients are required to sign an informed consent agreement before undergoing the procedure, stating that the patient understands the risk involved and the alternatives available. It is doubtful that desperately ill patients are given all the facts when considering xenograft procedures. In 1984, doctors at Loma Linda University in California transplanted a baboon heart into an infant born with serious heart defects. "Baby Fae" died 20 days later. Afterwards, an independent review panel determined that there were at least three other options-all more promising than a xenograft-available to treat her condition. The baby's mother, who was alone and virtually destitute, was never informed of these options.

Costly Failures

Xenografts divert precious resources away from truly life-saving efforts to prevent and treat disease. Each xenograft procedure costs between $250,000 and $300,000 to perform. The University of Pittsburgh's experimental transplant program receives more than $8 million each year in funding, largely through federal grants from the National Institutes of Health. Meanwhile, many promising new treatments for AIDS and other life-threatening diseases go unexplored because of a lack of funding. Ironically, national human organ donor procurement programs receive less than half a million dollars annually.

Promote Human Organ Donations

Advocates of cross-species transplants point to the dearth of human organ donors to justify continued efforts in this field. Every year, thousands of Americans are buried with organs that are suitable for donation, far exceeding the 3,400 who die while on organ donor waiting lists. In fact, an April 1998 General Accounting Office report on organ donation revealed an untapped donor pool of 150,000 people annually which leads many to believe that our government is not, as it claims, doing all it can to increase organ donation.

In contrast, countries like Spain, Austria, and Belgium have much higher donation rates than the U.S. due in part to the fact that European organ donor policies assume that every person is an organ donor unless otherwise specified. The burden rests with individuals (or their families) if they do not wish to donate their organs. Even within our current system, patients have a better chance of long-term survival by waiting for a last-minute human organ than by choosing a xenograft.

Conclusion

The Food and Drug Administration and the National Institutes of Health's policy on xenografts has essentially transformed planet earth into a giant experimental laboratory in which every taxpayer will be forced to participate in cruel, wasteful, and dangerous cross-species organ transplants. This policy appears to be based not on science, but the potential profits of the biomedical industry. If this policy were based on science, the FDA and NIH would admit that the risks of infectious disease posed by that of nonhuman primates and that of pigs are one in the same, that every one of these previous experiments has failed, that the tens of millions of dollars now wasted in the study of xenografts would be better spent on truly life-saving efforts to prevent and treat disease, and that they have failed to adequately promote human organ donations.

Therefore, we demand that the Department of Health and Human Services ban xenotransplantation immediately.

Sincerely,

Peter Wood

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Research Associate

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